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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,587	04/22/2008	Norihiro Yamaguchi	063140	5603
38834 7590 11/27/2009 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				
EXAMINER MCKANE, ELIZABETH L.				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary

Application No.

10/594,587

Applicant(s)

YAMAGUCHI ET AL.

Examiner

ELIZABETH L. MCKANE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Houillebecq et al. (GB 2,168,082).

Houillebecq et al. teaches an ink composition comprising a triarylmethane and/or anthraquinone dye and a cationic surfactant. See Abstract. The cationic surfactant may be an alkyl trimethylammonium chloride (page 3, line 42). In the absence of evidence to the contrary, the composition of Houillebecq et al. is capable of being used to detect an oxidizing gas.

3. Claims 1, 3, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumitami et al. (EP 1,312,918).

Sumitami et al. teaches a composition for detecting a gas wherein the composition comprises an organic colorant and a cationic surfactant. See Abstract. The organic colorant may be a thiazine dye (para [0011]) and the cationic surfactant is an alkyl trimethylammonium chloride (para [0010]). The composition is formed as a color changing layer on sheet silicate.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudou (JP 2002-303618) in view of Omatsu et al. (US 2001/0054374).

With respect to claims 1, 3-5, and 7, Sudou et al. teaches an ink composition for detecting an oxidizing gas (hydrogen peroxide plasma) containing a dye such as a triarylmethane dye (sulfophthalein). See paragraph [0007]. The composition of Sudou et al. further includes a binder (paragraph [0021]) and a color or paint which does not change color in an oxidizing gas atmosphere (paragraph [0025]). The composition is applied as a layer to a wrapping material. See paragraph [0008]. Sudou et al. is silent with respect to use of a cationic surfactant. Omatsu et al., however, discloses use of a cationic surfactant such as an alkyl trimethylammonium salt in an indicator containing an anthraquinone dye in order to obtain improved detection sensitivity when using an anthraquinone dye. See paragraph [0025]. For this reason, it would have been obvious to employ a cationic dye in the composition of Sudou et al. as one would have expected the cationic surfactant to have a similar effect on a triarylmethane dye.

As to claim 8, although Sudou et al. fails to teach a non-color changing layer, this is evidenced by Omatsu et al.. In fact, Omatsu et al. discloses that a non-color changing layer can assist in determining the end-point of the plasma sterilization

process (paragraphs [0037]-[0045]). Thus, one would have found it obvious to add a non-color changing layer to the indicator of Sudou et al..

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sudou and Omatsu et al. as applied to claim 1 above, and further in view of Nagata et al. (US 6,267,242).

Sudou et al. is silent with respect to use of an anthraquinone dye in combination with the triarylmethane dye. Nagata et al. discloses the use of an anthraquinone dye in a indicating composition for a hydrogen peroxide plasma process. See col.2, lines 43-54. Moreover, Nagata et al. teaches that two or more indicators may be combined. Sudou et al. also discloses that sterilization indicators may use a combination of two or more to achieve the desired hue in the indicator (paragraph [0020]). Thus, it would have been obvious to one of ordinary skill in the art to combine the use of an anthraquinone dye with the triarylmethane dye of Sudou in order to realize the desired color attributes of the indicator.

7. Claims 9, 12-17, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. in view of Antonoplos et al. (US 2002/0051733).

With respect to claims 9, 12-17, 21, and 23, Omatsu et al. teaches an ink composition for detecting hydrogen peroxide plasma sterilization (Abstract). The composition includes an anthraquinone dye (paragraph [0019]), a nitrogen-containing (amide) polymer (paragraph [0028]), and a cationic surfactant (paragraph [0024]). The cationic surfactant can be alkyltrimethylammonium salt (paragraph [0026]) and the composition may further include a cellulose resin binder and a silica extender. See

Example 1. The nitrogen-containing polymer (amide) may be used as a binder in an amount of 5-35 wt.%. See paragraph [0031]. Omatsu et al. further discloses that the ink composition may include a coloring material which does not change color in the plasma sterilization atmosphere (paragraph [0023]). In use, Omatsu et al. teaches that the ink composition is applied as a layer to a support and may further include a non-color changing layer. See paragraphs [0034]-[0037]. Omatsu et al. does not disclose use of an azo dye or a methane dye.

Antonoplos et al. discloses a chemical indicator for oxidative (hydrogen peroxide) sterilants wherein the indicator dye is an azo dye (paragraph [0016]). The dye may be coated onto a paper or plastic substrate in use (para [0037], [0100]). It would have been obvious to use the dye of Antonoplos et al. in combination with the dye of Omatsu et al., as Omatsu teaches that "dyes other than said anthraquinone dyes...may also be used concomitantly" (para [0023]) and since doing so would have provided redundancy for sterility assurance.

As to claim 22, although Omatsu et al. is silent with respect to cracks specifically in the layer, it is known and obvious in the art that 'cracks' often appear when printing dyes to substrates, forming as the ink dries.

8. Claims 10, 11, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. and Antonoplos et al. as applied to claim 9 above, and further in view of Sudou et al..

With respect to claims 10 and 11, Omatsu et al. teaches use of an amide resin, but is silent to a polyamide resin. Sudou et al. discloses the known use of a polyamide

resin in an indicator composition. See paragraph [0017]. It would have been obvious to one of ordinary skill in the art to use an amide known in the art as being an effective resin in indicator dye compositions. As to the particular polyamide, it is deemed obvious to one of ordinary skill in the art to choose an appropriate and known polyamide, especially where the results are not unexpected.

As to claim 20, Omatsu et al. fails to disclose an organic amine. Sudou et al. teaches that an organic amine can be used as a discoloration auxiliary agent. See paragraph [0023]. Likewise, it would have been obvious to add an organic amine to the composition of Omatsu et al. as the results of doing so would have been apparent to one skilled in the art.

9. Claims 18, 19, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. and Antonoplos et al. as applied to claims 9 and 21 above, and further in view of Lippold et al. (US 6,410,338).

With respect to claims 18, 19, and 24, Omatsu et al. is silent with respect to a component which changes color by reacting with hydrogen peroxide. Lippold et al. teaches an indicator for plasma sterilization wherein the indicator includes a salt of aurintricarboxylic acid (col.4, lines 46-48) and which changes color by reacting with hydrogen peroxide. As Omatsu et al. discloses that additional dyes may be used with the anthraquinone in the indicating composition, it would have been obvious to add the indicator of Lippold et al. to Omatsu et al. in order to provide a chemical indicator with redundancy.

As to claims 25 and 26, Omatsu et al. teaches that the layers may be applied so as to be overlapping or mutually exclusive. See paragraphs [0037]-[0045]. One of ordinary skill in the art would have been apprised of suitable printing patterns to optimize use of the indicator.

10. Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omatsu et al. in view of Antonoplos et al. Nagata et al..

Omatsu et al. with Antonoplos et al. teach use of the indicator composition within a sterilizer along with a load to be sterilized (paragraph [0048] of Omatsu et al.). Omatsu et al. does not disclose placing the indicator on an inner surface of a pouch. Nagata et al. discloses a non-woven polyethylene pouch having a transparent window wherein a chemical indicator is placed on an inner surface of the pouch such that the indicator can be viewed through the window. See col.4, lines 7-52. As gas-permeable bags are well-known in the art of sterilization as a means of containing a load to be sterilized, it would have been obvious to use the indicator of Omatsu et al. with Antonoplos et al. within a gas-permeable bag, as disclosed by Nagata et al..

Response to Arguments

11. The Declaration under 37 CFR 1.132 filed 4 August is insufficient to overcome the rejection of the claims based upon Sudou et al. and Omatsu et al. as set forth in the last Office action because: the experimental results submitted with the Declaration would seem to indicate that the addition of the cationic surfactant improves the detection sensitivity of a multitude of dyes. For example, when the cationic surfactant is

added to a dye the color change is more pronounced and/or occurs faster. However, this is the same teaching found in Omatsu et al.. Thus, it was already known in the art at the time of the invention that the addition of a cationic surfactant to a dye increases detection sensitivity. Although Omatsu et al. does not teach the use of dyes other than anthraquinone dyes, it would have been obvious to apply the same surfactant to other dyes with a reasonable expectation of success.

12. Applicant's arguments filed 4 August 2009 have been fully considered but they are not persuasive.

13. On page 11, of the Response Applicant states that the "Examiner concludes that it would have been obvious to employ a cationic dye in the composition of Sudou et al. because one would have found it obvious to add a non-color changing layer to the indicator of Sudou et al." This was not the Examiner's motivation. Applicant's attention is directed to page 4, numbered paragraph 8 of the Office Action dated 4 March 2009 or to numbered paragraph 5 of the instant Office Action. In fact, the Examiner's motivation to combine Sudou et al. with Omatsu et al. was/is to obtain the improved detection sensitivity disclosed by Omatsu et al..

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
22 November 2009